ORIGINAL

NEW CORRESP

NC

COLLAGENEX pharmaceuticals

ORIGINAL

Noted CCGilkes 10-4-96

September 17, 1996

Food & Drug Administration
Center for Drug Evaluation and Research
Documents and Records Section
12420 Parklawn Drive
Rockville, MD 20852

Attention: Jonathan K. Wilkin, M.D.
Director, Division of Dermatologic and Dental Drug Products
(HFD-540)

RE: Minor Amendment - NDA #50-744
Periostat™ (doxycycline hyclate capsules USP)

Dear Dr. Wilkin:

Please refer to our NDA #50-744 (originally submitted as NDA #20-642 on August 30, 1996) for Periostat™ (doxycycline hyclate, USP) 20 mg capsules which is proposed for use as part of a professional oral health program to promote periodontal attachment level gain and reduce bone loss, pocket depth and bleeding on probing in patients with adult periodontal disease..

At the request of Dr. Hal Blatt, CSO, HFD-540, CollaGenex is providing a revised cover letter and Form FDA 356h (8 copies)which has been changed to reflect the new NDA number and that the NDA is submitted pursuant to Section 507 of the Food, Drug and Cosmetic Act rather than Section 505.

If there are any questions concerning this application, please contact the undersigned at 215-579-7619 (telephone) or 215-579-8577 (fax).

Sincerely,

Christopher Powala

Christopher Powala
Director, Drug Development
& Regulatory Affairs

REVIEWS COMPLETED	
CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO	
CSO INITIALS	DATE

CollaGenex Pharmaceuticals, Inc., 301 South State Street, Newtown, PA 18940 USA
215-579-7388 voice 215-579-8577 fax

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 1990.
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS

NOTE: No application may be filed unless a completed application form has been received (21 CFR Part 314).

NAME OF APPLICANT	DATE OF SUBMISSION
CollaGenex Pharmaceuticals, Inc.	9/17/96
ADDRESS (Number, Street, City, State and Zip Code)	TELEPHONE NO (Include Area Code)
301 South State Street Newtown, PA 18940	(215) 579-7619
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (If previously issued)
	50-744

DRUG PRODUCT

ESTABLISHED NAME (e.g., USP/USAN)	PROPRIETARY NAME (If any)
doxycycline hyclate capsules USP	Periostat™

CODE NAME (If any)	CHEMICAL NAME
	4-(Dimethlamino)-1,4,4a,5,5a,6,11,12a-octahydo-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
capsule	oral	20mg

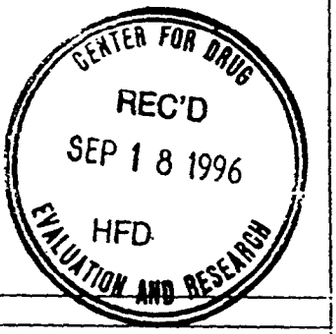
PROPOSED INDICATIONS FOR USE

Treatment of adult periodontitis

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS (21 CFR Part 312), NEW DRUG OR ANTIBIOTIC APPLICATIONS (21 CFR Part 314), AND DRUG MASTER FILES (21CFR 314.420) REFERRED TO IN THIS APPLICATION:

AADA 62-374
AADA 62-839

See Attachment 1 for Drug Master File References



INFORMATION ON APPLICATION

TYPE OF APPLICATION (Check one)

■ THIS SUBMISSION IS A FULL APPLICATION (21 CFR 314.50) ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

STATUS OF APPLICATION (Check one)

☐ PRESUBMISSION ORIGINAL APPLICATION ■ AN AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ SUPPLEMENTAL APPLICATION

PROPOSED MARKETING STATUS (Check one)

■ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT (Rx) ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT (OTC)

CONTENTS OF APPLICATION	
This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Summary (21 CFR 314.50 (c))
	3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))
	4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
	b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))
	c. Labeling (21 CFR 314.50 (e) (2) (ii))
	i. draft labeling *(4 copies)*
	ii. final printed labeling (12 copies)
	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))
	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))
	7. Microbiology section (21 CFR 314.50 (d) (4))
	8. Clinical data section (21 CFR 314.50 (d) (5))
	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
	10. Statistical section (21 CFR 314.50 (d) (6))
	11. Case report tabulations (21 CFR 314.50 (f) (1))
	12. Case reports forms (21 CFR 314.50 (f) (1))
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
X	15. OTHER *(Specify)* **Minor Amendment**

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211.
2. Labeling regulations in 21 CFR 201.
3. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.
4. Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.
5. Regulations on reports in 21 CFR 314.80 and 314.81.
6. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
Christopher V. Powala Director, Drug Development & Regulatory Affairs	Christopher V. Powala	9/17/96

ADDRESS *(Street, City, State, Zip Code)*	TELEPHONE NO. *(Include Area Code)*
CollaGenex Pharmaceuticals, Inc. **301 S. State Street, Newtown, PA 18940**	(215) 579-7619

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)